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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,325	04/24/2001	Mark Modell	MDS-009CN (6219/15)	6590
51414	7590	12/19/2005		
GOODWIN PROCTER LLP			EXAMINER	
PATENT ADMINISTRATOR			SMITH, RUTH S	
EXCHANGE PLACE				
BOSTON, MA 02109-2881			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/841,325	MODELL ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Ruth S. Smith	3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 December 2005.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 105-111,113,115-119,121-126,148,150,152-156,159,160 and 162-168 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 105-111,113,115-119,121-126,148,150,152-156,159,160 and 162-168 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date 12/1/05.
- 4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 105-111,113,118,121-125,148,150,152-156,162-166,168 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeBaryshe et al in view of Svetkoff et al. DeBaryshe et al disclose an optical system for analyzing tissue including means for illuminating and collecting optical radiation in a substantially confocal configuration. The illuminating means and detecting means includes arrays and moveable mirrors and field stops as set forth in the claims. DeBaryshe et al fails to specifically disclose the specific type of field stop used. Svetkoff et al is just one example of many which discloses the use of a field stop which comprises an electromechanical shutter (column 7, lines 50-68). It would have been obvious to one skilled in the art to have modified DeBaryshe et al such that the field stops used comprise electromechanical shutter devices. Such a modification merely involves the substitution of one known type of field stop for another.

Claims 105-107,109,110,115,125,126,150,152-156,159-160,162,165-167 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zavislans ('852) in view of Svetkoff et al. Zavislans discloses an optical system for diagnosing tissue using a confocal illuminating and detecting arrangement. Zavislans discloses an optical system for diagnosing tissue using a confocal illuminating and detecting arrangement. The sheath can comprises the elements shown in figures 9-11 which prevent the imager 83 from contacting the tissue. The sheath is capable of being used only a single time and can be disposed of. The imager used in the apparatus of Zavislans is disclosed as that of US Patent No. 5,788,639 which includes beam splitters/mirrors which are moveable

with respect to the patient. Zavislans et al disclose that cervical tissue can be examined. It is well known to access the cervical tissue using equipment such as an endoscope, laproscope etc in order to provide a non-invasive type of device. The use of such would prevent additional harm from coming to the patient by avoiding surgical intervention and would therefore have been obvious to one skilled in the art. in the art. It would have been obvious to one skilled in the art that the apparatus of Zavislans would have been applicable to any tissue type. With respect to claims 121, 162, the specific field stop dimension used would have been an obvious design choice of known equivalents in the art. Having the tissue not be surgically exposed does not add patentable weight to the apparatus claims. Zavislans fails to specifically disclose the specific type of field stop used. Svetkoff et al is just one example of many which discloses the use of a field stop which comprises an electromechanical shutter (column 7, lines 50-68). It would have been obvious to one skilled in the art to have modified Zavislans such that the field stops used comprise electromechanical shutter devices. Such a modification merely involves the substitution of one known type of field stop for another.

Claims 108,111,113,118,119,123,148,168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zavislans et al ('852) in view of Svetkoff et al as applied to claims 105,107 above, and further in view of Kittrell et al. Zavislans discloses an optical system for diagnosing tissue using a confocal illuminating and detecting arrangement. Zavislans fails to disclose comparing the data obtained to a standard and the use of moveable mirrors to scan the tissue. It is well known in the medical art to obtain data from a tissue region and compare the data to at least one standard in order to properly diagnose the tissue region being tested. An example of such is seen in Kittrell et al. Kittrell et al disclose a method of optically analyzing tissue. Kittrell et al disclose illuminating the tissue using an optical assembly comprising moveable mirrors to focus the light on different regions of tissue. The structure set forth in claim 118,119 is seen in figure 23, elements 68,70. It would have been obvious to one skilled in the art to have further modified Zavislans such that the data obtained is analyzed by comparing such to a known standard in order to provide a diagnosis of the tissue being tested.

Furthermore, it would have been obvious to have scanned the tissue sample by using moveable mirrors rather than mechanically translating the imager. Such a modification involves the substitution of one known type of scanning means for another. With respect to claim 121 and 162, the specific field stop dimension used would have been an obvious design choice of known equivalents in the art.

Claims 116,117,122,124,163,164 rejected under 35 U.S.C. 103(a) as being unpatentable over Zavislan ('852) in view of Svetkoff et al and Kitterell et al as applied to claims 108, 152 above, and further in view of Raz. Raz discloses a confocal imaging system which uses an array of emitters and detectors in order to scan a large region of interest. It would have been obvious to one skilled in the art to have further modified Zavislan such that an array of detectors is used in order to scan a larger region of interest in a short time period. Inasmuch as Zavislan discloses the use of optical devices, the array of detectors would require the use of optical elements and processors. The use of an array of detectors and emitters would result in an array of field stops.

#### *Response to Arguments*

Applicant's arguments with respect to claims 105-111,113,115-119,121-126,148,150,152-156,159-160,162-168 have been considered but are moot in view of the new ground(s) of rejection.

#### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth S. Smith  
Primary Examiner  
Art Unit 3737

RSS